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Asthma research claims life of test participant

The death of a healthy 24-year-old woman who received US$365 to participate in asthma-related research has again raised questions about how adequately medical research participants are informed and protected. The research at the Johns Hopkins Bayview Medical Center in Baltimore, where Ellen Roche worked as a laboratory technician, was suspended just before her death June 2.

Researchers induced asthmatic reactions in people without asthma to study the possible protective physiologic mechanisms of deep breathing on normal lungs. In the baseline physiologic test, Roche and 2 other volunteers inhaled hexamethonium, a ganglion blocker that disables the protective mechanism of lung relaxation induced by deep breathing.

Roche signed an informed-consent form that warned of possible wheezing, chest tightness and temporary difficulty in breathing. Within a month of inhaling hexamethonium, she died of acute respiratory distress syndrome and renal failure.

The initial investigation by the Office for Human Research Protection found that researchers had violated safety procedures by failing to report a previous adverse reaction, failing to get Food and Drug Administration permission for the subjects to inhale hexamethonium and failing to inform volunteers that they were inhaling an experimental, unapproved drug.

Since 1998, concerns about patient safety have halted clinical trials at medical schools at universities in Oklahoma, Alabama, North Carolina and Massachusetts. The death of 18-year-old Jesse Gelsinger (*CMAJ* 2001;164[11]:1612) during a gene-therapy trial in September 1999 led the University of Pennsylvania to stop using human subjects in its genetic research. The investigation into Roche's death continues, but in July the Office for Human Research Protections suspended almost all federally funded research at Johns Hopkins. The office ruled that the ethics committee that had approved the study involving Roche had failed to take proper precautions to protect its subjects. However, the suspension lasted only 4 days, and was lifted July 23. — *Barbara Sibbald*, CMAJ

CONFERENCE REPORT

Putting patient safety on the health care agenda

Today marked your first visit to the renal failure clinic. You saw a doctor, at least 1 nurse, then someone who talked about food. A kind team coordinator wrote out your instructions, which looked like this:

Mr. Jones:
#$&^#R53$R @345s $%*bl) and @!!@##%#$%.
*Begin with @###($^%$., hjj%%&dv, 334%&^!#$^ and +&**#g#4d.*

It had been a very long day. You took the instructions, knowing that your wife would help sort them out. She usually has to help, since you are among the 20% of adults considered fully illiterate. Unfortunately, your wife is in the subgroup (28%) of functionally illiterate adults that comes next. This means she cannot even read the front page of a newspaper. So what do you do now?

Literacy issues like this were but one topic during the Annenberg III conference in Minneapolis in mid-May, where the almost 700 attendees were seeking ways to improve patient safety and reduce risks and harm in medical care.

We learned that effective communication with patients is a key factor in achieving this, but the task becomes daunting if a medical error occurs and a patient is harmed. The question then becomes: Should we share this information with patients? The National Patient Safety Foundation (NPSF), a US not-for-profit organization founded in part by the American Medical Association, believes we should. Its Statement of Principle reads: "When a health care injury occurs the patient and the family . . . are entitled to a prompt explanation of how the injury occurred and its short and long-term effects. When an error contributed to the injury, [they] should receive a truthful and compassionate explanation about the error and the remedies available to the patient. They should be informed that the factors involved in the injury will be investigated so that steps can be taken to reduce the likelihood of similar injury to other patients."

The conference participants, who included physicians, nurses and risk managers, heard several moving presentations by patients who had been injured while receiving medical care and saw videotaped examples of how to discuss errors, as well as a simulated mediation case.

Presenters pointed out that a team-based collaborative approach is needed to introduce the changes required to prevent errors, but existing systems usually rely on a punitive "blame-and-shame" approach that does not lead to effective learning or change.

There was little argument about the ethical duty of health care workers to disclose errors, although there are many practical barriers to this. A Kentucky hospital that instituted a "patient bill of rights" 8 years ago found that its policy of prompt and full disclosure of errors has actually decreased the liability costs arising from them. However, a major cultural change will be required before changes like that become widespread.

The good news for physicians is that discussion of this topic has finally begun. The bad news for Canada is that only 11 of the almost 700 participants at the Minneapolis meeting were Canadian.

For further information on this subject, visit **www.mederrors.org**, **www.annenberg.net** or **www.npsf.org**. — This meeting coverage was provided by Dr. *Rob Robson*, an Ottawa emergency physician/mediator with a special interest in health care liability issues.